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EXAMINER
MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/019,387	DALLE CARBONARE ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 3-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, Amendments and IDS filed on 10/01/2007 is acknowledged.

Claims 3 and 4 have been amended and new claim 18 has been added in this Application. Accordingly, claims **3-18** are pending in this application, claims **3-18** will be prosecuted on the merits.

The rejections made under 35 USC 112.1 have been withdrawn in view of applicant's arguments. The rejection made under 35 USC 112.2 has been withdrawn in view of Applicant's amendments to the claims.

The following are new rejections made in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating wound and normotrophic scarring, does not reasonably provide enablement for reducing the extent of normotrophic scarring as claimed in claim 3 and reducing the extent of wounds to the skin as claimed in claim 4. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Reducing the extent of normotrophic scar or reducing the extent of wounds to skin reads on prevention of scarring which is caused due to the reduction of extent of wounds forever. The phrase "reducing the extent of" can be read as reducing to any level which can also be to level where no scariing is present at al. The instant disclosure only provides guidance towards treatment of the wound and reduction in scarring during the process of wound healing.

For rejections under 35 U.S.C. 112, first paragraph, the following factors are considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

I) Nature of the invention.

II) State of prior art.

III) Level of ordinary skill in the art.

IV) Level of predictability in the art.

V) Amount of direction and guidance provided by the inventor.

VI) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

I. Nature of the invention:

The claims are drawn to reducing the extent of scarring or extent of wound but the data in the specification only show the treatment of wound and scarring during wound healing process.

II. State of the prior art:

The prior art does not disclose case supported by data showing the reduction in extent of scarring or extent of wound healing to the degree where it is reduced to the level of zero, where the reoccurrence is not possible.

III. Level of Ordinary Skill in the art:

The level of ordinary skill in the art is high. Applicants' specification does not enable the public to practice the art of keeping scarring from reducing to the extent of zero or absolute.

IV. Level of predictability:

Since applicants' specification does not show the reducing the extent of scarring or extent of wound, the ability of the person of skill in the art is challenged to extrapolate the disclosed or known results to the claimed invention with little or no predictability. The lower the predictability, the higher the direction and guidance that must be provided by

the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants.

V. Amount of direction and guidance provided by the inventors:

The amount of direction and guidance provided by the applicants is limited to reducing the extent of scarring or reducing the extent of wound .

VI. Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The quantity of experimentation required to use the invention as claimed, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experimentation with a large number of subjects and for reliable duration of time during which the reduction in extent of scarring or reduction in extent of wound is shown to take place to the extent where it is treated to the limit of prevention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "wherein said scarring is normotrophic scarring". There is no antecedent basis for this phrase. Claim 5 is dependent on claim 4. Claim 4 does not state anything about scarring. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/04828 ('828) in view of WO 94/17837 ('837) and further in view of Jeffrey et al. (Clinical materials (1991) and Yashwant et al. (Biomaterials (1996).

'828 disclose compositions comprising hyaluronic acid derivatives and methods of using said hyaluronic acid-based compositions to treat the formation of post-surgical adhesion and scar formation (abstract and page 51). Like the instant application, '828 discloses that the following set of hyaluronic acid derivatives can be used to treat adhesion and scar formation: (1) hyaluronic acid derivatives esterified with alcohols; (2) autocrosslinked esters of hyaluronic acid; (3) crosslinked hyaluronic acid compounds; (4) hemiesters of succinic acid; (5) N sulphated derivatives of hyaluronic acid; and (6) amide derivative.s of hyaluronic acid (See page 4, lines 1-28). The above hyaluronic

acid derivatives can be formulated as gels and additional pharmacologically active substances, such as antibiotics, may also be used in the method (Claims 1-33).

'828 does not specifically teach skin scar treatment.

However, ('837) teaches a multilayer nonwoven material, comprising a surface layer which comes into contact with the skin, and one or more other layers which do not come into contact with the skin, wherein said surface layer which comes into contact with the skin is at least one derivative of hyaluronic acid. The derivative of hyaluronic acid is hyaluronic acid ester (abstract). Examples 1-7 on page 7 depict the use of hyaluronic acid benzyl ester. ('837) further discloses that the multilayer nonwoven materials are used in dermatology such as treating the skin pathologies (page 3, lines 22-24 and claim 30).

Jeffrey teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced scarring (see title and page 171, second column).

Yashwant teaches application of benzyl hyaluronate as wound dressings (see title and the whole article).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use hyaluronic acid ester for the treatment of scarring on the skin by using the composition provided by ('828). Since (837) teaches the treatment of skin pathologies, Jeffrey teaches utilization of hyaluronate esters in wound healing and scarring treatment and Yashwant teaches application of esters of hyaluronic acid as wound dressing. A skilled artisan would have been motivated to use derivatives of

hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

7. Applicant's arguments with respect to claims 17 have been considered but are moot in view of the new ground(s) of rejection.

8. Claims 3-10 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/07833 ('833) in view of WO 94/17837 ('837) and further in view of Jeffrey et al. (Clinical materials (1991) and Yashwant et al. (Biomaterials (1996).

'833 discloses hyaluronic acid derivatives capable of being used for post-surgical adhesion (abstract). As set forth in '833, an "adhesion" is a permanent scar that connects two adjacent surfaces (page 2, lines 1-10). Like the instant application, '828 discloses that the following set of hyaluronic acid derivatives can be used to treat adhesion and scar formation: (1) hyaluronic acid derivatives esterfied with alcohols; (2) autocrosslinked esters of hyaluronic acid; 'and (3) crosslinked hyaluronic acid compounds (page 9, lines 1-12; page ;12, Example 3; page 14, lines 1-35; page 30, lines 29-35and page 31, lines 1-25;).The above hyaluronic acid derivatives can be formulated as gels and additional pharmacologically active substances, such as heparin, may also be used the method (Claims 1, 10 and page 31, Table 1).

('833) does not specifically teach skin scar treatment.

However, ('837) teaches a multilayer nonwoven material, comprising a surface layer which comes into contact with the skin, and one or more other layers which do not come into contact with the skin, wherein said surface layer which comes into contact with the skin is at least one derivative of hyaluronic acid. The derivative of hyaluronic acid is hyaluronic acid ester (abstract).). Examples 1-7 on page 7 depict the use of hyaluronic acid benzyl ester (page 3, lines 22-24 and claim 30).

('837) further discloses that the multilayer nonwoven materials are used in dermatology such as treating the skin pathologies.

Jeffrey teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced scarring (see title and page 171, second column).

Yashwant teaches application of benzyl hyaluronate as wound dressings (see title and the whole article).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use hyaluronic acid ester for the treatment of scarring on the skin by using the composition provided by ('833) as (837) teaches the treatment of skin pathologies, Jeffrey teaches utilization of hyaluronate esters in wound healing and scarring treatment and Yashwant teaches application of esters of hyaluronic acid as wound dressing. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

9. Applicant's arguments with respect to claims 3-10 and 12-17 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to

5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

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